K002586

NOV 17 2000

510(k) SUMMARY

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (770) 423-1437

Contact: Howard Mercer, Ph.D.
e-mail: howard _mercer@porex.com

Date: August 17, 2000

Trade Name: MEDPOR® Pterional Surgical Implant
Classification Name; Ear, nose and throat synthetic polymer material - Class II Device

Substantially equivalent to:
A) MEDPOR® Preformed Shapes by Porex Surgical Inc.

Device description:

A Pterional Surgical Implant that is made of porous polyethylene and is anatomically shaped, to minimize the amount of carving and reshaping required by the surgeon to match the implant site.

Comparison with predicate device

The device of this submission is identical to the predicate device in all aspects except for dimensional changes and the claim that it is appropriate for the repair of Pterional defects.

Indications for Use:

The Pterional Implant is indicated to correct temporal hollowing in patients who have had surgery involving the Pterional approach to the cranium, including Pterional craniotomy. The Pterional Implant augments the space normally occupied by the temporalis muscle. The implant is used for the reconstruction of temporal contour deformities; the reconstruction of temporal craniotomy defects, and/or the augmentation/reconstruction of the space normally occupied by the temporalis muscle/temporal area(s).

The MEDPOR Pterional Implant may be modified by carving with a scalpel or burr as needed to fit the individual patient. Fixation of the implant to the cranial bone with craniofacial screws is recommended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 7 2000

Howard Mercer, Ph.D.
Porex Surgical Products Group
15 Dart Road
Newnan, Georgia 30265

Re: K002586
Trade Name: MEDPOR® Pterional Surgical Implant
Regulatory Class: II
Product Code: MNF
Dated: August 17, 2000
Received: August 21, 2000

Dear Dr. Mercer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002586

Applicant: Porex Surgical Inc.

510(k) Number : K002586

Device Name: MEDPOR® Pterional Surgical Implant

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(PLEASE DO NOT WRITE BELOW THIS LINE)

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR801.109

MRO for CDRH
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002586